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APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/652,302 08/28/2000		Robert W. Mah	ARC-14231-2	2337	
25186	7590 08/21/2002				
	S RESEARCH CENT	EXAMINER			
MAIL STOP		MCCROSKY, DAVID J			
MOFFETT FI	ELD, CA 94035-1000		ART UNIT	PAPER NUMBER	
		3736			
		DATE MAILED: 08/21/2002			

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application	No.	Applicant(s)	<del></del>			
Office Action Summary		09/652,302		MAH, ROBERT W.				
		Examiner		Art Unit				
		David J. McC	crosky	3736				
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status								
1)⊠	Responsive to communication(s) filed on 29 August 2001.							
2a) <u></u> □	This action is <b>FINAL</b> . 2b)⊠ Thi	is action is no	n-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims								
4)⊠ Claim(s) 1-42 is/are pending in the application.								
•	4a) Of the above claim(s) <u>21-42</u> is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.								
6)⊠ Claim(s) <u>1-20</u> is/are rejected.								
· · · · · · · · · · · · · · · · · · ·	laim(s) is/are objected to.							
	laim(s) are subject to restriction and/or	r election req	uirement.		•			
Application Papers								
9) The specification is objected to by the Examiner.								
10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.								
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.								
If approved, corrected drawings are required in reply to this Office action.								
12)☐ The oath or declaration is objected to by the Examiner.								
Priority under 35 U.S.C. §§ 119 and 120								
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).								
a) All b) Some * c) None of:								
1. Certified copies of the priority documents have been received.								
2	2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).								
* See the attached detailed Office action for a list of the certified copies not received.								
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).								
<ul> <li>a) ☐ The translation of the foreign language provisional application has been received.</li> <li>15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</li> </ul>								
Attachment(s)								
2) Notice	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) tion Disclosure Statement(s) (PTO-1449) Paper No(s) 5	1		(PTO-413) Paper No( Patent Application (PTC				
J.S. Patent and Trad		ction Summary		Part of	Paper No. 8			

Art Unit: 3736

### **DETAILED ACTION**

Following notification and proof by Applicant that a preliminary amendment received August 29, 2001 had not been matched with the application, the amendment was entered and examined as follows. Applicant should disregard the first office action mailed February 1, 2002, which did not consider the unmatched preliminary amendment.

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1-20, drawn to a system and method for performing measurements using a probe, classified in class 600, subclass 300.
- II. Claims 21-42, drawn to a system and method of estimating a medical condition using databases and a computer, classified in class 600, subclass 300.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention II has separate utility such as estimating a medical condition using measurements from sensors such as an EEG or MRI. See MPEP § 806.05(d).

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Art Unit: 3736

During a telephone conversation with Robert Padilla on August 6, 2002 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-20. Affirmation of this election must be made by applicant in replying to this Office action. Claims 21-42 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Mah et al. The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention

Art Unit: 3736

"by another," or by an appropriate showing under 37 CFR 1.131. The reference teaches a system and method of measuring physiological characteristics using a probe having several sensors. See col. 7, I. 45 to col. 8, I. 11 and claim 12. Other measurements are combined with the sensor data. See col. 4, II. 13-33 and col. 5, II. 7-19. The reference further discloses a neural network, which is trained using reference tissues and continually updated. See col. 10, II. 48-59 and col. 11, II. 6-10. The neural network defines a normal range and thereby identifies abnormal tissue, which is outside the range. The neural network classifies the tissue or malady. See col. 11. The strain gauge and Doppler blood flow sensors are used to navigate the probe. See col. 8, II. 62-67. Optical reflectance sensors are used to obtain characteristics of tissue. See col. 3, II. 54-65 and col. 10.

Claims 1 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Gardosi. The reference discloses a probe having an ECG and oximetry sensors on the surface of the probe. See col. 3, II. 45-52 and claim 4.

#### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 9-11, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shine et al in view of Gardosi. Shine et al teach that it is well known in the art to monitor both maternal and fetal vital signs using ultrasound, ECG and pulse

Art Unit: 3736

oximetry. See col. 1, II. 8-15. Shine et al further teach a system and method to implement the described monitoring. See col. 2. The processor determines characterizations of data using trend analysis. See col. 3. Shine et al do not teach a probe comprising an ECG and oximeter. However, Gardosi teach a probe comprising an ECG and oximetry sensor. See col. 3, II. 45-52 and claim 4. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system and method of Shine et al with the probe taught by Gardosi in order to facilitate measurement of fetal vital signs.

### Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 3736

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4-9 and 12-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 9, 12, 14, 15 and 17-20 of U.S. Patent No. 6,109,270 issued to Mah et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims disclose a system and method of measuring physiological characteristics using a probe having several sensors. See claim 12. The reference further claims a neural network, which is trained using reference tissues and continually updated. The neural network defines a normal range and thereby identifies abnormal tissue, which is outside the range. The neural network classifies the tissue or malady. See claims 15 and 17-19. Optical reflectance sensors are used to obtain characteristics of tissue. See claim 9. The sensors are used to navigate the probe. See claims 14 and 20.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. McCrosky whose telephone number is 703-305-1331. The examiner can normally be reached on Mon-Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on 703-308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

Art Unit: 3736

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

DJM August 15, 2002

> ERIC F. WINAKUR PRIMARY EXAMINER